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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,210	08/22/2006	Mary R. Boone	59404US004	4407

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EXAMINER	
MINSKEY, JACOB T	

ART UNIT	PAPER NUMBER
1791	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/590,210	BOONE ET AL.	
	Examiner	Art Unit	
	JACOB T. MINSKEY	4151	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12,15-21,23 and 26-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12,15-21,23 and 26-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/26/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lastovich, US Patent publication 2004/0007796 A1.

3. Regarding claim 29, this claim is a product by process claim, see MPEP § 2113. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself (i.e., differences in product characteristics), and not on its method of production. In the present instance, all that is claimed is a product, which is shown by Lastovich (microneedle [0011]).

4. Regarding claim 30, this claim is a product by process claim, see MPEP § 2113. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself (i.e., differences in product characteristics), and not on its method of production. In the present instance, all that is claimed is a drug delivery device, which is shown by Lastovich (described in [0005]).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 3, 5-10, 12, 16-19, 21, 23, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lastovich, US Patent publication 2004/0007796 A1 in view of Clarke et al, WO 2004/009172 (already of record).

9. Regarding claim 1, Lastovich teaches a method of manufacturing a molded microneedle array (micro-device and microneedles [0011]) comprising: providing a negative mold insert characterized by a negative image of microneedle topography [0034-0037]; transferring the negative mold insert into an injection molding apparatus [0034], wherein the negative mold insert is exposed and defines a structured surface of a negative mold cavity [0034-0037]; heating the negative mold cavity to a temperature above the softening temperature of a moldable plastic material [0048]; heating the moldable plastic material to at least the molten temperature of the moldable plastic material in a chamber separate from the negative mold cavity [0048]; injecting the molten plastic material into the heated negative mold cavity [0048], allowing the molten plastic material to fill at least about 90 percent of the volume of the negative indentations defined by the negative mold insert (as described in [0046] to completely enter the recesses of the mold); cooling the molten plastic material to a temperature below the softening temperature of the moldable plastic material (cold runners may be used [0045]); and detaching the molded microneedle array from the negative mold insert [0049].

10. Lastovich also teaches that his method of creating microprotusion devices have a range of 0.5 to 500 microns [0026]. Lastovich does not explicitly state that at least one

negative image of a microneedle is characterized by an aspect ratio of between about 2 to 1 and about 5 to 1, but he does teach a range that can accomplish the claimed ratio.

11. In the same field of endeavor of producing microneedles, Clarke et al teach that at least one negative image of a microneedle is characterized by an aspect ratio of between about 2 to 1 and about 5 to 1 (page 11 lines 3-14) for the benefit of avoiding the sensation of pain by penetrating the skin without stimulating the underlying nerve tissue (page 10 lines 26-31).

12. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Clarke's use of a specific aspect ratio in the Lastovich method for the benefit of avoiding the sensation of pain by penetrating the skin without stimulating the underlying nerve tissue.

13. Regarding claim 3, Lastovich and Clarke remain as applied in claim 1 and Lastovich further teaches that the negative mold insert is formed by: providing a positive mold master (master [0040]) member characterized by microneedle topography wherein at least one microneedle is characterized by an aspect ratio of between about 2 to 1 and about 5 to 1; electroforming [0040] a negative mold insert around the positive mold master; and detaching the negative mold insert from the positive mold master member [0040].

14. Regarding claim 5, Lastovich and Clarke remain as applied in claim 1 and Lastovich further teaches that the negative mold insert is fabricated by nickel electroforming [0040].

15. Regarding claim 6, Lastovich and Clarke remain as applied in claim 3 and Lastovich further teaches that the microneedle topography of the positive mold master member is prepared by diamond turning [0035].

16. Regarding claim 7, Lastovich and Clarke remain as applied in claim 1, and Clarke further teaches that wherein the microneedle array comprises a plurality of microneedles each having a flat tip comprising a surface area measured in a plane aligned with the base of about 20 square micrometers or more and 100 square micrometers or less (page 3 lines 1-6).

17. Regarding claim 8, Lastovich and Clarke remain as applied in claim 1, and Clarke further teaches that the microneedle array is formed as part of a larger array (see figure 1), wherein at least a portion of the larger array comprises a non-patterned substrate (arranged in any desired pattern or distributed over the surface randomly, page 7 lines 13-16 see figures 1 and 2, see also Lastovich figure 6).

18. Regarding claim 9, Lastovich and Clarke remain as applied in claim 8, but do not explicitly teach that the non-patterned substrate has an area of more than about 0.10 square inch (0.65 cm2) to less than about 1 square inch (6.5 cm2).

19. It would have been obvious to one of ordinary skill in the art at the time of the invention to make the non-patterned substrate has an area of more than about 0.10 square inch (0.65 cm2) to less than about 1 square inch (6.5 cm2), since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235). On would have been motivated to

provide the claimed range of non-patterned surface area for the benefit of providing a density control means as well as an area of skin contact that does not include penetration of the skin.

20. Regarding claim 10, Lastovich and Clarke remain as applied in claim 1, and while Lastovich does not explicitly state that the microneedle array comprises a plurality of molded microneedles having a height greater than about 90 percent of the corresponding height of the microneedle topography in the negative mold insert, Lastovich does teach the molding method [0042-0047] that includes etching to make sure the mold is same size as the master [0042] and removal of air through either vents or vacuum to ensure complete filling of the microstructures with material [0046].

21. One or ordinary skill in the art at the time of the invention would have the ability to follow Lastovich's teachings to achieve the result of obtaining microneedles of at least 90% of the mold depth.

22. Regarding claim 12, Lastovich and Clarke remain as applied in claim 1, and Lastovich further teaches that the moldable plastic material comprises a material selected from the group consisting of polycarbonate, polystyrene, polyethylene, polypropylene, and blends thereof (polystyrenes, [0032]).

23. Regarding claim 16, Lastovich and Clarke remains as applied in claim 1, and Lastovich further teaches that the microneedle array comprises a plurality of microneedles having a pyramidal shape (trapezoidal [0030]).

24. Regarding claim 17, Lastovich and Clarke remain as applied in claim 1, but do not explicitly teach that the molten plastic material is injected into the heated negative mold cavity with a velocity of less than 2.0 in/see (5.08 cm/sec).

25. It would have been obvious to one of ordinary skill in the art at the time of the invention to inject the plastic material into the heated negative mold cavity with a velocity of less than 2.0 in/see (5.08 cm/sec), since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235). On would have been motivated to provide the claimed range of injection speed for the benefit of slowly filling the cavity to insure a complete fill of the mold.

26. Regarding claim 18, Lastovich and Clarke remain as applied in claim 17, and while Lastovich teaches compressing the mold under high pressure [0049] Lastovich is silent on an actual value for the pressure.

27. It would have been obvious to one of ordinary skill in the art at the time of the invention to compress the plastic material into the heated negative mold cavity at a pressure of at least 6000 psi, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235). On would have been motivated to provide the claimed range of pressure for the benefit of consolidating the material in the mold.

28. Regarding claim 19, Lastovich teaches that the negative mold insert is formed by: providing a positive mold master (master [0040]) member; electroforming [0040] a negative mold insert around the positive mold master; and detaching the negative mold insert from the positive mold master member [0040].

29. Lastovich also teaches that his method of creating microprotusion devices have a range of 0.5 to 500 microns [0026]. Lastovich does not explicitly state that at least one negative image of a microneedle is characterized by an aspect ratio of between about 2 to 1 and about 5 to 1, but he does teach a range that can accomplish the claimed ratio.

30. In the same field of endeavor of producing microneedles, Clarke et al teach that at least one negative image of a microneedle is characterized by an aspect ratio of between about 2 to 1 and about 5 to 1 (page 11 lines 3-14) for the benefit of avoiding the sensation of pain by penetrating the skin without stimulating the underlying nerve tissue (page 10 lines 26-31).

31. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Clarke's use of a specific aspect ratio in the Lastovich method for the benefit of avoiding the sensation of pain by penetrating the skin without stimulating the underlying nerve tissue.

32. Regarding claim 21, Lastovich and Clarke remain as applied in claim 19 and Lastovich further teaches that the negative mold insert is fabricated by nickel electroforming [0040].

33. Regarding claim 23, Lastovich and Clarke remain as applied in claim 19, and Clarke further teaches that wherein the microneedle array comprises a plurality of

microneedles each having a flat tip comprising a surface area measured in a plane aligned with the base of about 20 square micrometers or more and 100 square micrometers or less (page 3 lines 1-6).

34. Regarding claim 26, Lastovich and Clarke remain as applied in claim 19, and Lastovich further teaches a method of manufacturing a molded microneedle array (micro-device and microneedles [0011]) comprising: providing a negative mold insert prepared according to claim 19; transferring the negative mold insert into an injection molding apparatus [0034], wherein the negative mold insert is exposed and defines a structured surface of a negative mold cavity [0034-0037]; providing a heated plastic material into the negative mold cavity [0048]; injecting the molten plastic material into the heated negative mold cavity [0048], allowing the molten plastic material to fill at least about 90 percent of the volume of the negative indentations defined by the negative mold insert (as described in [0046] to completely enter the recesses of the mold); cooling the molten plastic material to a temperature below the softening temperature of the moldable plastic material (cold runners may be used [0045]); and detaching the molded microneedle array from the negative mold insert [0049].

35. Regarding claim 27, Lastovich and Clarke remain as applied in claim 26, and Lastovich further teaches that the molding apparatus is an injection molding apparatus [0032].

36. Claims 2, 15, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lastovich, US Patent publication 2004/0007796 A1 in view of Clarke et al, WO

2004/009172 and in further view of Sherman et al, US Patent Publication 2002/0020688 A1.

37. Regarding claim 2, Lastovich teaches a method of manufacturing a molded microneedle array (micro-device and microneedles [0011]) comprising: providing a negative mold insert characterized by a negative image of microneedle topography [0034-0037]; transferring the negative mold insert into an injection molding apparatus [0034], wherein the negative mold insert is exposed and defines a structured surface of a negative mold cavity [0034-0037]; heating the moldable plastic material to at least the molten temperature of the moldable plastic material in a chamber separate from the negative mold cavity [0048]; injecting the molten plastic material into the heated negative mold cavity [0048], allowing the molten plastic material to fill at least about 90 percent of the volume of the negative indentations defined by the negative mold insert (as described in [0046] to completely enter the recesses of the mold); cooling the molten plastic material to a temperature below the softening temperature of the moldable plastic material (cold runners may be used [0045]); and detaching the molded microneedle array from the negative mold insert [0049].

38. Lastovich also teaches that his method of creating microprotusion devices have a range of 0.5 to 500 microns [0026]. Lastovich does not explicitly state that at least one negative image of a microneedle is characterized by an aspect ratio of between about 2 to 1 and about 5 to 1, but he does teach a range that can accomplish the claimed ratio.

39. In the same field of endeavor of producing microneedles, Clarke et al teach that at least one negative image of a microneedle is characterized by an aspect ratio of

between about 2 to 1 and about 5 to 1 (page 11 lines 3-14) for the benefit of avoiding the sensation of pain by penetrating the skin without stimulating the underlying nerve tissue (page 10 lines 26-31).

40. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Clarke's use of a specific aspect ratio in the Lastovich method for the benefit of avoiding the sensation of pain by penetrating the skin without stimulating the underlying nerve tissue.

41. While Lastovich and Clarke teach heating a mold to a materials softening point, they do not explicitly teach heating the negative mold cavity to a temperature of more than about 10 degrees centigrade above the softening temperature of a moldable plastic material.

42. In the same field of endeavor of manufacturing microneedles, Sherman et al teach heating the mold to above the melting temperature of the plastic material [0061] for the benefit of making the material completely melt off the top of the mold creating hollow needles [0061].

43. It would have been obvious to one of ordinary skill in the art at the time of the invention that heating a material above its melting point as taught by Sherman would provide the same benefits of a more malleable material as heating the mold to at least 10 degrees above the softening point.

44. Regarding claim 15, Lastovich, Clarke, and Sherman remain as applied in claim 2, and Sherman et al further teach heating the mold to above the melting temperature of

the plastic material [0061] for the benefit of making the material completely melt off the top of the mold creating hollow needles [0061].

45. It would have been obvious to one of ordinary skill in the art at the time of the invention that heating a material above its melting point as taught by Sherman would provide the same benefits of a more malleable material as heating the mold to at least 30 degrees above the softening point.

46. Regarding claim 28, Lastovich and Clarke remains as applied in claim 26. While Lastovich and Clarke teach heating a mold to a materials softening point, they do not explicitly teach heating the negative mold cavity to a temperature of more than about 10 degrees centigrade above the softening temperature of a moldable plastic material.

47. In the same field of endeavor of manufacturing microneedles, Sherman et al teach heating the mold to above the melting temperature of the plastic material [0061] for the benefit of making the material completely melt off the top of the mold creating hollow needles [0061].

48. It would have been obvious to one of ordinary skill in the art at the time of the invention that heating a material above its melting point as taught by Sherman would provide the same benefits of a more malleable material as heating the mold to at least 10 degrees above the softening point.

49. Claims 4, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lastovich, US Patent publication 2004/0007796 A1 in view of Clarke et al, WO 2004/009172 and in further view of Hoopman et al, USP 6,076,248.

50. Regarding claim 4, Lastovich and Clarke remain as applied in claim 3, but do not teach that the positive mold master member comprises copper.

51. In the same field of endeavor of manufacturing microneedles, Hoopman et al teach that the positive mold master member comprises copper (column 13 lines 4-22) for the benefit of providing a conductive and strong master for repeated use.

52. It would have been obvious to one of ordinary skill in the art at the time of the invention to use Hoopman's copper positive mold master in the Lastovich method for the benefit of providing a conductive and strong master for repeated use.

53. Regarding claim 20, Lastovich and Clarke remain as applied in claim 19, but do not teach that the positive mold master member comprises copper.

54. In the same field of endeavor of manufacturing microneedles, Hoopman et al teach that the positive mold master member comprises copper (column 13 lines 4-22) for the benefit of providing a conductive and strong master for repeated use.

55. It would have been obvious to one of ordinary skill in the art at the time of the invention to use Hoopman's copper positive mold master in the Lastovich method for the benefit of providing a conductive and strong master for repeated use.

Conclusion

56. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

57. US Patent publication 2006/0202385 to Yuan et al teaches the fabrication of microneedles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB T. MINSKEY whose telephone number is (571)270-7003. The examiner can normally be reached on Monday to Friday 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Ortiz can be reached on 571-272-1206. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JTM

/Angela Ortiz/

Supervisory Patent Examiner, Art Unit 4151